UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BAYER SCHERA PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

– v. –

SANDOZ, INC., WATSON PHARMACEUTICALS, INC., and WATSON LABORATORIES, INC.,

Defendants.

08 Civ. 03710 (PGG)

MEMORANDUM OPINION AND ORDER

PAUL G. GARDEPHE, U.S.D.J.

In this action, Bayer Schera Pharma AG and Bayer Healthcare Pharmaceuticals Inc. (collectively "Bayer") allege that Defendants' proposed marketing of generic versions of Bayer's brand-name oral contraceptive Yasmin will infringe on Bayer's patent rights. Bayer initiated this litigation after Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Watson"), and Defendant Sandoz, Inc. filed Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") to market generic versions of Yasmin. (See Cmplt. ¶¶ 14, 15) Bayer alleges that Defendants' ANDA filings constitute infringement and inducement of infringement of U.S. Patent No. 5,569,652 ("the '652 patent"), which Bayer holds. (Cmplt. ¶¶ 20, 21, Ex. 1)

Defendants have moved for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). (Docket No. 78) Under well established Federal Circuit precedent, Bayer cannot state a patent infringement claim based on Defendants' ANDA filings unless it can show that the '652 patent claims a use for Yasmin that has been approved by the

FDA under Bayer's New Drug Application ("NDA") for Yasmin. For the reasons stated below, this Court has determined that the '652 patent does not claim a use for Yasmin that has been approved by the FDA. Accordingly, Defendants' motion for judgment on the pleadings will be GRANTED.

BACKGROUND

Watson and Sandoz each filed ANDAs seeking permission to market a generic version of Yasmin (Cmplt. ¶¶ 14, 15), and both submitted Paragraph IV certifications to the FDA alleging that Bayer's patents are invalid or will not be infringed by the use, manufacture, or sale of a generic version of Yasmin. (Id. ¶¶ 18, 19) Watson and Sandoz each sent statutorily-required ANDA notice letters to Bayer in March 2008. (Id. ¶¶ 18, 19) On April 17, 2008, Bayer filed the instant action against Defendants for infringement of the '652 patent. (Id. ¶¶ 20, 21) Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Bayer's filing of this action triggered an automatic thirty-month stay on the FDA's approval of Defendants' respective ANDAs. The thirty-month stay as to each ANDA expired earlier this month.[1]

Bayer's Complaint asserts claims against Defendants for infringement and inducement of infringement of the '652 patent under 35 U.S.C. § 271(e)(2)(A), which provides that it "shall be an act of infringement to submit [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent." (See Cmplt. ¶¶ 22-32, 36-46) Bayer also alleges that the Defendants' intended sale of a generic version of Yasmin will induce infringement of the '652 patent in violation of 35 U.S.C. § 271(b), which provides

[1] On September 2, 2010, this Court denied Bayer's motion to extend the statutory thirty-month stay with respect to Watson's ANDA. See Bayer Schera Pharma AG v. Sandoz, Inc., No. 08 Civ. 3710(PGG), 2010 U.S. Dist. LEXIS 91849 (S.D.N.Y. Sept. 2, 2010).

that whoever "actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b).

Bayer alleges that the '652 patent – the "patent-in suit" – claims a use for Yasmin that has been approved by the FDA. (Cmplt. ¶ 21; Bayer Br. 1-2, 12-24) In support of this argument, Bayer notes that – in connection with its NDA for Yasmin – it notified the FDA that the '652 patent claims the drug for which it sought approval. As a result, the FDA listed the '652 patent in its Approved Drug Products with Therapeutic Equivalence Evaluations text ("the Orange Book"). (Cmplt. ¶¶ 20-21)

Claim 11 of the '652 patent – which is the central patent claim at issue in this case[2] – asserts the following "method-of-use" claim for Yasmin:

> A method of simultaneously achieving, during pre-menopause or menopause, a contraceptive effect, an anti-androgenic effect, and an anti-aldosterone effect in a female patient in need thereof comprising administering an effective amount of dihydrospirorenone and an effective amount of an estrogenic compound, wherein said effective amount of dihydrospirorenone is effective to simultaneously achieve a gestagenic effect, anti-androgenic effect, and an anti-aldosterone effect in said female patient.

(Cmplt., Ex. 1 ('652 Patent, Claim 11))[3]

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[2] Defendants argue that Claim 11 of the '652 patent is the only relevant claim. (Def. Br. 10 n.7) In a footnote, Bayer states that it "does not concede that claim 11 is the only relevant claim," and notes that Defendants have "infringe[d] several other claims of the '652 patent" and that "Bayer chose [to discuss] claim 11 for illustrative purposes." (Bayer Br. 12 n.7) The Complaint, however, only makes reference to those claims in the '652 patent that relate to simultaneously achieving a gestagenic, anti-androgenic, and anti-aldosterone effect. (See ¶¶ 25-28, 39-42) In any event, to the extent that other claims in the '652 patent relate to simultaneously achieving a gestagenic, anti-androgenic, and anti-aldosterone effect, this Court has determined that Yasmin is not FDA-approved for this trio of uses, and that instead, it has only been approved for use as an oral contraceptive.

[3] "Gestagenic" refers to a contraceptive effect. (Bayer Ex. 3 (Shulman Decl.), ¶ 20)

DISCUSSION

I. MOTION TO DISMISS STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'"[4]

Aldosterone is defined as "[a] steroid hormone secreted by the adrenal cortex that regulates the salt and water balance in the body." Dorland's Medical Dictionary for Health Consumers (2007), http://medical-dictionary.thefreedictionary.com/aldosterone (last visited Sept. 24, 2010). "Anti-aldosterone" effect refers to an inhibitory effect on the "renin-angiotensin-aldosterone system," which influences electrolyte balance in the body and impacts a number of bodily functions, including fluid retention. (Bayer Ex. 3 (Shulman Decl.), ¶¶ 13-14)

Anti-androgenic is defined as "[a] substance that blocks the action of androgens, the hormones responsible for male characteristics." Dorland's Medical Dictionary for Health Consumers (2007), http://medical-dictionary.thefreedictionary.com/antiandrogen (last visited Sept. 24, 2010). "Anti-androgenic" effect refers to the inhibition of the action of testosterone and other androgens on androgen receptors, which apparently can lead to a reduction in facial hair or acne. (Bayer Ex. 3 (Shulman Decl.), ¶¶ 13-14)

[4] In ruling on Defendants' motion, this Court has considered – in addition to the Complaint – "those documents attached to the pleadings as an exhibit or any statements or documents incorporated in the Complaint by reference, and . . . any documents that are integral to the Complaint or an appropriate subject for judicial notice." D'Antonio v. Metro. Transp. Auth., No. 06 Civ. 4283 (KMW), 2008 U.S. Dist. LEXIS 16726, at *10 n.6 (S.D.N.Y. Mar. 4, 2008) (citing Global Network Commc'ns, Inc. v. City of New York, 458 F.3d 150, 154-56 (2d Cir. 2006))) This Court may consider the above-listed documents without converting Defendants' Fed. R. Civ. P. 12(c) motion to a motion for summary judgment. See, e.g., Kamholtz v. Yates County, 350 F. App'x 589, 591-92 (2d Cir. 2009); Chambers v. Time Warner, Inc., 282 F.3d 147, 152-53 (2d Cir. 2002) ("'The complaint is deemed to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference.' Even where a document is not incorporated by reference, the court may nevertheless consider it where the complaint 'relies heavily upon its terms and effect,' which renders the document 'integral' to the complaint." (quoting Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co., 62 F.3d 69, 72 (2d Cir. 1995) (per curiam))).

Pursuant to this standard, this Court has considered: (1) Bayer's '652 patent; (2) the FDA-approved labeling for Yasmin (Def. Ex. C); (3) the FDA approval letter for the NDA Bayer submitted in connection with Yasmin (Def. Ex. B); and (4) the proposed labels Defendants submitted to the FDA in connection with their ANDA filings. The '652 patent is attached as an exhibit to the Complaint. (Cmplt., Ex. 1 ('652 Patent)) The

Ashcroft v. Iqbal, 556 U.S. --, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). To meet this standard, a complaint's factual allegations must permit the Court, "draw[ing] on its judicial experience and common sense," "to infer more than the mere possibility of misconduct." Id. at 1950. "In considering a motion to dismiss . . . the court is to accept as true all facts alleged in the complaint," Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir. 2007) (citing Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 87 (2d Cir. 2002)), and must "draw all reasonable inferences in favor of the plaintiff." Id. (citing Fernandez v. Chertoff, 471 F.3d 45, 51 (2d Cir. 2006)). However, "threadbare recitals of a cause of action, supported by mere conclusory statements, do not suffice [to establish entitlement to relief]." Iqbal, 129 S.Ct. at 1949. Motions for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) are considered under the same standards "'applicable to a motion under Rule 12(b)(6).'" King v. Am. Airlines, Inc., 284 F.3d 352, 356 (2d Cir. 2002) (quoting Burnette v. Carothers, 192 F.3d 52, 56 (2d Cir. 1999)).

II. THE ANDA FRAMEWORK

"The Hatch-Waxman Act strikes a balance between two potentially competing policy interests – inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term." Novo

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FDA's approval of Bayer's NDA for Yasmin, and the FDA's approval of Yasmin tablets, is referenced in the Complaint. (Cmplt. ¶ 13) The Complaint also makes reference to the proposed labels Watson and Sandoz submitted to the FDA (Def. Exs. E, F) in connection with their ANDA filings. (Cmplt. ¶¶ 14-15, 26-27, 40-41) All of the above-mentioned documents are likewise integral to the Complaint.

Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1360 (Fed. Cir. 2010) (citing Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

"The Hatch-Waxman Act . . . requires a pioneer drug manufacturer to notify the FDA of all patents that 'claim [ ] the drug for which the [NDA] applicant submitted the application.'" Eli Lilly & Co. v. Teva Pharm. USA, Inc., 557 F.3d 1346, 1348 (Fed. Cir. 2009) (quoting 21 U.S.C. §§ 355(b)(1) & (c)(2)). "The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations, known as the 'Orange Book.'" Id. Pursuant to the Hatch-Waxman Act, "a generic manufacturer infringes a patent . . . by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent." Id. (citing 35 U.S.C. § 271(e)(2)).

"A manufacturer that seeks to market a generic drug may submit an ANDA for approval by the [FDA], rather than submitting a full New Drug Application ('NDA') showing the safety and efficacy of the generic drug." Eli Lilly & Co., 557 F.3d at 1348. "The ANDA process streamlines FDA approval by allowing the generic manufacturer to rely on the safety and efficacy studies of a drug already in the Orange Book upon a showing of bioequivalence." Novo Nordisk A/S, 601 F.3d at 1361.

"As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug." Eli Lilly & Co., 557 F.3d at 1348. In that certification, "the generic manufacturer must select one of four alternatives permitting use of the patented product or process: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be

infringed by the manufacture, use, or sale of the generic drug." Novo Nordisk A/S, 601 F.3d at 1361 (citing 21 U.S.C. § 355(j)(2)(A)(vii)). "These are commonly referred to as paragraph I, II, III, and IV certifications." Eli Lilly & Co., 557 F.3d at 1348.

"If a generic manufacturer wishes to seek FDA approval for a use not covered by a method-of-use patent for a listed drug, it must make a 'section viii statement.'" Novo Nordisk A/S, 601 F.3d at 1361 (citing 21 U.S.C. § 355(j)(2)(A)(viii)). "Along with the section viii statement, the generic manufacturer must submit a proposed label to the FDA that does not contain the patented method of using the listed drug. When considering approval of these requests for a use not covered by a patent, the FDA relies on the applicable patent's use code narrative to determine the scope of the patented method." Id. (citing 68 Fed. Reg. 36676, 36682 (June 18, 2003)). "The FDA approves the section viii statement only where there is no overlap between the proposed carve-out label submitted by the generic manufacturer and the use code narrative submitted by the pioneering manufacturer." Id. at 1361-62.

Here, Watson and Sandoz each filed an ANDA seeking permission to market a generic version of Yasmin (Cmplt. ¶¶ 14, 15), and both submitted Paragraph IV certifications alleging that Bayer's patents are invalid or will not be infringed by the use, manufacture, or sale of a generic version of Yasmin. (Id. ¶¶ 18, 19) "When an ANDA certifies under paragraph IV, the applicant must provide the patentee a detailed basis for its belief that the patent is not infringed, that it is invalid, or that it is unenforceable." Eli Lilly & Co., 557 F.3d at 1348 (citing 21 U.S.C. § 355(j)(2)(B)). "The patentee then has forty-five days to sue the ANDA applicant for patent infringement." If no suit is filed, the FDA may "proceed to approve the ANDA." Id. (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

If the patentee files suit within the forty-five day period, "the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier." Id. (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

"[A] generic drug manufacturer may file an ANDA before a patent expires and, in so doing, allege non-infringement and invalidity of the patent." Allergan Inc. v. Alcon Labs., 324 F.3d 1322, 1326 (Fed. Cir. 2003) (per curiam). "The Hatch-Waxman Act provides that, in that situation, the filing of the ANDA is an act of infringement." Id. (citing 35 U.S.C. § 271(e)(2)(A); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568-69 (Fed. Cir. 1997)). The Hatch-Waxman Act therefore "allows a generic drug manufacturer to take the steps needed to bring a generic drug to market without waiting until the patent expires," while at the same time – by treating the filing of an ANDA as an act of infringement – "allow[ing] a brand name drug manufacturer to challenge the ANDA application and a generic drug manufacturer to challenge the validity and infringement of an asserted patent before the patent expires." Id.

35 U.S.C. § 271(e)(2) "simply provides an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003). To establish inducement liability under 35 U.S.C. § 271(b), "a patent holder must prove that once the defendant knew of the patent, it 'actively and knowingly aid[ed] and abett[ed] another's direct infringement.'" Takeda Pharm. Co. Ltd. v. Takeda Pharm. N. Am., Inc., No. 07 Civ. 3844 (DLC), 2007 U.S. Dist. LEXIS 74860, at *8 (S.D.N.Y. Oct.

9, 2007) (quoting Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)). "[K]nowledge of the acts alleged to constitute infringement" is insufficient; "specific intent and action to induce infringement must be proven." Warner-Lambert, 316 F.3d at 1363-64 (citation omitted).

III. DEFENDANTS ARE ENTITLED TO JUDGMENT ON THE PLEADINGS

Defendants contend that "a method-of-use patent holder, such as Bayer may not bring an action under 35 U.S.C. § 271(e)(2) for infringement of a method-of-use patent that does not claim a use approved by the FDA under the patent-holder's New Drug Application ('NDA')." (Def. Br. 2) Defendants further argue that Bayer's § 271(b) inducement claim fails, because a method-of-use patent holder "may not sue an ANDA applicant under 25 U.S.C. § 271(b) for inducing infringement of its patent if the ANDA applicant is not seeking FDA approval for the use claimed in the patent and if the use claimed in the patent is not FDA-approved." (Id.)

Bayer does not dispute these legal principles. (Bayer Br. 1) Instead, Bayer argues that "[t]he Generics lose this motion because Yasmin is FDA-approved for oral contraception plus the two additional pharmacological effects [i.e., an anti-androgenic effect, and an anti-aldosterone effect]." (Bayer Br. 8-9) Although the "Indications and Usage" section of Yasmin's FDA-approved label states that "YASMIN is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive" and mentions no other indication or use (Def. Ex. C (Yasmin Label)), Bayer contends that "patented FDA-approved uses may reside outside (even wholly outside) the Indications section of the label." (Bayer Br. 2) In the alternative, Bayer contends that the issue of

whether the '652 patent's method-of-use has been FDA-approved presents "a question of fact unsuitable for resolution on the pleadings." (Id.)

In arguing that Yasmin is FDA-approved for the method-of-use covered by the '652 patent, Bayer cites to, inter alia, the "Clinical Pharmacology" section of Yasmin's FDA-approved label, to the fact that the '652 patent is listed in the Orange Book, and to its marketing materials, which apparently promote Yasmin for uses other than oral contraception. None of these arguments, however, refutes undisputed evidence – including the "Indications and Usage" section of Yasmin's FDA-approved label and the FDA's letter approving Bayer's NDA for Yasmin – that Yasmin is only FDA-approved for use as an oral contraceptive. Bayer cites no law for the novel proposition that the FDA-approved indication for a drug can be expanded by references on the label to side effects noted in pre-clinical studies, by a listing in the Orange Book, or by – of all things – a pharmaceutical company's promotional materials for its drug.

The "Indications and Usage" section of Yasmin's FDA-approved label, as well as the FDA's letter approving Bayer's NDA for Yasmin, make clear – as a matter of law – that the FDA has approved Yasmin only for use as an oral contraceptive. Because the only FDA-approved use of Yasmin is oral contraception, and because the FDA has not approved the method-of-use set forth in the '652 patent, Defendants are entitled to judgment on the pleadings concerning Bayer's infringement claims.

A. Section 271(e)(2)(A) Claims

1. Applicable Law

In Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003), the Federal Circuit considered "whether it is an act of infringement under 35 U.S.C. §

271(e)(2)(A) to submit an ANDA seeking approval to make, use, or sell a drug for an approved use if any other use of the drug is claimed in a patent, or if it is only an act of infringement to submit an ANDA seeking approval to make, use, or sell a drug if the drug or the use for which FDA approval is sought is claimed in the patent." 316 F.3d at 1354 (emphasis in original). The Warner-Lambert court concluded that "it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." Id. at 1354-55. Stated another way, the Warner-Lambert court "held that a method of use patent holder may not bring an action under section 271(e)(2) for infringement of a method of use patent that does not claim a FDA-approved use." Allergan, 324 F.3d at 1333-34; see also Warner-Lambert, 316 F.3d at 1354 ("Congress clearly intended to limit actions for infringement of method-of-use patents under §271(e)(2)(A) to 'controlling use patents,' or patents that claim an approved use of a drug.").

In Warner-Lambert, Apotex – a generic manufacturer – filed an ANDA seeking approval to market a generic formulation of the drug gabapentin at the expiration of Warner-Lambert's epilepsy method patent. 316 F.3d at 1352. Warner-Lambert – which marketed gabapentin under the trade name "Neurontin" – also held rights to a second method-of-use patent for gabapentin (the "neurodegenerative method patent"), which covered the use of gabapentin to treat certain neurodegenerative diseases. Id. at 1351-52. Apotex's ANDA sought approval to market gabapentin for "the same indication for which Warner-Lambert's Neurontin . . . was approved, i.e., for 'adjunctive

therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy.'" Id. at 1352.

In connection with its ANDA, Apotex filed a paragraph IV certification, which represented that its generic product would not infringe Warner Lambert's neurodegenerative method-of-use patent, because Apotex was not seeking approval to use gabapentin for the treatment of neurodegenerative diseases, but only for the treatment of epilepsy. Id. at 1353. Warner-Lambert nonetheless sued Apotex for patent infringement, contending that Apotex's ANDA infringed on Warner-Lambert's neurodegenerative method patent under § 271(e)(2) and that Apotex would induce infringement under §271(b). In the subsequent litigation, the parties did not dispute that the FDA had approved gabapentin only for use in treating epilepsy, and had not approved it for use in treating neurodegenerative diseases, the method-of-use claimed in Warner-Lambert's patent. Id. at 1362

Warner-Lambert contended that under § 271(e)(2), "a patent claiming a use of a drug is infringed by the filing of an ANDA irrespective of whether approval is sought to market the drug for the patented use." Id. at 1355. This argument was soundly rejected:

> Warner-Lambert's proposed interpretation is inconsistent with both of the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress clearly did not intend to confer. If Warner-Lambert's interpretation were correct, for example, an NDA holder would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA. It would then be able to use section 271 (e)(2)(A) as a sword against any competitor's ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent. Generic manufacturers would effectively be precluded altogether from entering the market.

Id. at 1359.

Warner-Lambert has consistently been cited for the proposition that an infringement claim against an ANDA filer cannot be premised on a method-of-use patent where that use is not FDA-approved. See, e.g., Allergan, 324 F. Supp. at 1334 ("Under Warner-Lambert, Allergan is precluded from suing [generic manufacturers] under section 271(e)(2) for inducing infringement of the '415 and '741 patents, because [the generic manufacturers] are not seeking FDA approval for the uses claimed in the patents and because the uses claimed in the patents are not FDA-approved."); Takeda Pharm. N. Am., Inc., 2007 U.S. Dist. LEXIS 74860, at *13 ("[T]he holding of Warner-Lambert that 'the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise)' is read to apply only when the request refers 'to a patent on an unapproved use.'" (quoting Warner-Lambert, 316 F.3d at 1364-65)); TorPharm, Inc. v. Thompson, 260 F. Supp. 2d 69, 74 (D.D.C. 2003) ("[U]nder Warner-Lambert, an ANDA applicant who is not seeking approval for the use covered by the patent in question, where that use has not been approved by the FDA, is not subject to suit under § 271(e)(2)(A)." (citing Warner-Lambert, 316 F.3d at 1354-55)); Alcon Labs. v. Allergan, Inc., 256 F. Supp. 2d 1080, 1086 (C.D. Cal. 2003) ("'[I]t is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA.'" (quoting Warner-Lambert, 316 F.3d at 1354)); ICN Pharms. v. Geneva Pharms., 272 F. Supp. 2d 1028, 1037 (C.D. Cal. 2003) ("Method of use infringement actions under

Section 271(e)(2) are limited to those involving 'controlling use patents,' i.e., patents that claim an FDA-approved use of a drug." (citing Warner-Lambert, 316 F.3d at 1362)).

2. Bayer Fails to State a Claim for Patent Infringement Because Yasmin is Only FDA-Approved for Oral Contraception

Under Warner-Lambert, the critical question in resolving the instant motion is whether Yasmin is FDA-approved for the method-of-use claimed in the '652 patent – i.e.,

> A method of simultaneously achieving, during pre-menopause or menopause, a contraceptive effect, an anti-androgenic effect, and an anti-aldosterone effect in a female patient in need thereof comprising administering an effective amount of dihydrospirorenone and an effective amount of an estrogenic compound, wherein said effective amount of dihydrospirorenone is effective to simultaneously achieve a gestagenic effect, anti-androgenic effect, and an anti-aldosterone effect in said female patient.

(Cmplt., Ex. 1 ('652 Patent, Claim 11))

As an initial matter, Bayer claims that when Defendants filed paragraph IV certifications in connection with their ANDA filings,[5] "they certified that they sought approval for the '652 patented use." (Bayer Br. 7) Defendants contend, however, that they "propose to market their generic versions of Yasmin exclusively for the drug's approved, and unpatented, indication of contraception." (Def. Br. 2)

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[5] Bayer argues that Defendants' filing of Paragraph IV certifications – rather than section viii statements – constitutes an admission that the FDA has approved the '652 patent method-of-use. (Bayer Br. 1, 2) Bayer cites no authority for the proposition that this Court should base its determination concerning the scope of FDA approval on the ANDA filings of a generic competitor.

The issue of whether Defendants should have filed section viii statements rather than Paragraph IV certifications is for the FDA. If Bayer is correct, then presumably the FDA will reject the ANDA applications. That issue, however, has little bearing on the question this Court must resolve: whether the FDA has approved the method-of-use set forth in the '652 patent.

Nothing in the proposed labels submitted in connection with Defendants' ANDA filings indicates that they seek FDA approval to market their generic drugs for the '652 patented use. (See Defs. Ex. E, F). To the contrary, Defendants' proposed labeling addresses only an indication for oral contraception. (Id.; Defs. Br. 13) This is hardly surprising, because Defendants could not obtain FDA approval to market generic versions of Yasmin for anything other than its FDA-approved use, which Defendants contend is limited to oral contraception. See Warner-Lambert, 316 F.3d at 1356 ("The FDA does not grant across-the-board approval to market a drug. Rather, it grants approval to make, use, and sell a drug for a specific purpose for which that drug has been demonstrated to be safe and efficacious. . . . That is . . . the only use for which an ANDA applicant can seek approval." (emphasis in original); id. at 1352 ("As mandated by 21 U.S.C. §355(j)(2)(A)(i), Apotex sought approval to market gabapentin only for the same indication for which Warner-Lambert's Neurontin was approved. . . .").

As to the scope of Yasmin's FDA-approved use, Bayer argues that "[t]he FDA has interpreted the relevant Hatch-Waxman statutes to encompass 'uses' broader than just an indication. In both its formal regulations and practice the FDA has acknowledged that FDA-approved 'uses' can be in portions of the labeling other than the Indications section." (Bayer Br. 13) Bayer's argument that the FDA has approved the '652 patent's claim of simultaneous gestagenic, anti-androgenic, and anti-aldosterone effect is founded on the following excerpt from the "Clinical Pharmacology" section of the Yasmin label:

> Drospirenone is a spironolactone analogue with antimineralocorticoid activity. Preclinical studies in animals and in vitro have shown that drospirenone has no androgenic, estrogenic, glucocorticoid, and

> antiglucocorticoid activity. Preclinical studies in animals have also shown that drospirenone has antiandrogenic activity.

(Defs. Ex. C (Yasmin Label); Bayer Br. 18) Bayer's argument that these label references to animal and in vitro studies constitute FDA approval for the use of Yasmin for its anti-androgenic and anti-aldosterone effects – i.e., that the FDA has found use of Yasmin safe and efficacious to achieve these effects – is frivolous.

As noted above, the "Indications and Usage" section of Yasmin's FDA-approved label states that "YASMIN is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive" and mentions no other indication or use. (Def. Ex. C (Yasmin Label)) The FDA letter approving Bayer's NDA for Yasmin also makes clear that Yasmin has been found safe and effective for oral contraception, and not for other purposes:

> This new drug application provides for the use of Yasmin ® Tablets (drospirenone 3 mg/ethinyl estradiol 0.030 mg) for oral contraception. We have completed the review of this application, as amended, . . . and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text.

(Def. Ex. B (FDA Approval Ltr.) (emphasis added))

The FDA approves the marketing of prescription drugs for specific purposes that have been proven safe and effective through highly rigorous clinical trials. As noted in Warner-Lambert, "[t]he FDA does not grant across-the-board approval to market a drug. Rather, it grants approval to make, use, and sell a drug for a specific purpose for which that drug has been demonstrated to be safe and efficacious." Warner-Lambert, 316 F.3d at 1356; see also ICN Pharms. v. Geneva Pharms. Tech. Corp., 272 F. Supp. 2d 1028, 1034 (C.D. Cal. 2003) ("In order to market a drug for a particular use, a

drug manufacturer must obtain FDA approval through the submission of a new drug application ('NDA') that includes the results of extensive testing, safety information, efficacy information, and composition data.").

The purpose of the FDA-approved label – as to indications and usage – is to clearly communicate what uses have been proven safe and effective, and FDA regulations explicitly provide that other uses and indications not listed in the "Indications and Usage" section of the label may not be implied based on other sections of the label, such as the Clinical Pharmacology section:

> [f]or drug products other than biological products, all indications listed in [the "Indications and Usage"] section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.26(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

21 C.F.R. § 201.57(c)(2)(iv) (emphasis added).[6]

Bayer also argues that because the '652 patent is listed in the Orange Book – reflecting the fact that Bayer, in connection with its NDA for Yasmin, notified the FDA that the '652 patent claims the drug for which it sought approval – the FDA has approved the uses claimed in the '652 patent. (Bayer Br. 14) A number of courts have recognized, however, that the Orange Book and the patents listed therein do not reliably indicate what

[6] Bayer argues that this labeling regulation was not in effect when the FDA approved Yasmin. While the FDA approval letter for Yasmin submitted by the parties is undated, (see Def. Ex. B (FDA Approval Ltr.)), it appears that Yasmin was approved on May 11, 2001. (See Def. Req. for Judicial Notice dated Nov. 16, 2009) While it is true that drug products approved prior to June 30, 2001, are subject to the labeling requirements set forth in 21 C.F.R. § 201.80 rather than the provision cited above, (see 21 C.F.R. § 201.56(b)(2)), Section 201.80 contains the same language as 21 C.F.R. § 201.57(c)(2)(iv): "Indications or uses must not be implied or suggested in other sections of labeling if not included in this section." Compare 21 C.F.R. § 201.80(c)(2)(i) with 21 C.F.R. § 201.57(c)(2)(iv).

uses of a drug are FDA-approved, in part because the FDA takes the NDA-holders at their word as to which patents claim FDA-approved uses. See Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1080 (D.C. Cir. 2001) ("The FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources, has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders' patent declarations and following their listing instructions."); Organon Inc. v. Teva Pharms., Inc.. 244 F. Supp. 2d 370, 374 n.6 (D.N.J. 2002) ("Generic manufacturers determine whether there is a patent that may be applicable to their ANDAs by reference to the 'Orange Book,' in which patent-owners list their patents in order to provide such notice. Despite that FDA regulations require that 'for patents that claim a method of use the applicant shall submit information [to the Orange Book] only on those patents that claim indications or other conditions of use of a pending or approved [NDA],' 21 C.F.R. §314.53(b), it is common for pioneers to list any and every patent they can obtain in the Orange Book so as to force generic manufacturers to file paragraph IV certifications. The FDA does not appear to have policed this practice."). Accordingly, listings in the Orange Book are not a reliable indicator of what uses of a drug have received FDA approval.

Alcon Labs. v. Allergan, 256 F. Supp. 2d 1080 (C.D. Cal. 2003), supports this Court's determination that the FDA-approved use of a drug is governed by the "Indications and Usage" section of its label, rather than listings in the Orange Book. In that case, Allergan – the pioneer company – had obtained FDA approval to market the drug Alphagan as a treatment for glaucoma, and specifically to reduce intraocular pressure ("IOP"). Allergan scientists later discovered, however, that the drug also had

neuroprotective properties such that applying it to nerve cells made them less susceptible to injury and degeneration. The drug itself was not protected by patent, but Allergan applied for and was granted patents relating to the drug's newly-discovered neuroprotective use. Allergan listed these patents in the Orange Book and gave notice that these new patents were related to the FDA-approved use of Alphagen for IOP. Generic companies then filed ANDAs with the FDA seeking to market generic versions of the drug, with the same FDA labeling requirements approved for Alphagan. Allergan sued the generic companies alleging patent infringement. Id. at 1082-1084.

Applying Warner-Lambert, the Alcon Labs. court stated that "Allergan's claim . . . cannot be predicated on a non-controlling use patent." Alcon Labs., 256 F. Supp. 2d at 1086. In an attempt to circumvent the Warner-Lambert holding, Allergan argued that "the use claimed under the ANDA is covered by the . . . Patent-in-suit." Id. Allergan claimed that "there is a distinction between the label for Alphagan®, on the one hand, and the approved use for [the drug], on the other." Id. The Court, however, flatly rejected this argument:

> Although Allergan indicates that the Alphagan® label states that the product is "indicated for lower intraocular pressure in patients with open-angle glaucoma or ocular hypertension," Allergan contends that the use of [the drug] for neuroprotection to treat open-angle glaucoma is also an approved method of use. The Court finds no support for this argument, either in the product label for Alphagan® or in the FDA approval letter for Alphagan®.

Id.

Alcon Labs. is on all fours with the instant action. Like Bayer, Allergan attempted to avoid the holding of Warner-Lambert by arguing that its drug was FDA-approved for uses beyond the "Indications and Usage" section of the Alphagan label.

The court examined the FDA-approved label for Alphagen and the FDA letter approving Allergan's NDA for Alphagen, found no indication for the use contemplated by the patent-in-suit, and rejected Allergan's argument. This Court has conducted the same analysis and reaches the same conclusion.[7] Defendants are entitled to judgment on the

[7] In support of its argument that the scope of FDA approval for Yasmin presents at least a question of fact, Bayer has submitted declarations from an obstetrician and a former FDA official who was involved in the approval process for Yasmin. This Court is convinced based upon the Complaint and its exhibit, the documents incorporated and referenced therein, and documents integral to the Complaint, however, that the instant action must be dismissed. The Court is not required to consider the additional exhibits submitted by Bayer. Miller v. Potter, No 07-CV-1767 (JFB) (ETB), 2007 U.S. Dist. LEXIS 95688, at *11 n.5 (E.D.N.Y. Nov. 29, 2007) ("[A]lthough the Court could convert the motion to dismiss to a motion for summary judgment and consider the Sturm Declaration, the Court need not do so."); Gomez v. Warden of Otisville Corr. Facility, No. 99 Civ. 9954, 2000 U.S. Dist. LEXIS 14508, at *2 n.1 (S.D.N.Y. Sept. 29, 2000) ("The parties have submitted affidavits and documentary exhibits in support of their submissions. The Court declines to consider matters outside of those permissible under Rule 12(b)(6), and chooses not to convert the motion to dismiss into one for summary judgment pursuant to Rule 56. . . . [T]his motion can be decided solely on the allegations in the Complaint, which make it clear that the Complaint must be dismissed." (citing Int'l Audiotext Network v. Am. Tel. Co., 62 F.3d 69, 72 (2d Cir. 1995) (per curiam); Crawford v. New York City Bd. of Educ., No. 99 Civ. 925, 1999 WL 1072495, at *1 (S.D.N.Y. Nov. 29, 1999))).

Even if the Court were to consider Bayer's additional exhibits, however, they in no way refute the overwhelming evidence that Yasmin is FDA-approved only for oral contraception. For example, the obstetrician's alleged belief that claim 11 of the '652 patent reflects an "on-label" use for Yasmin (see Bayer Ex. 3 (Shulman Decl.) at ¶¶ 19-24) – because the anti-androgenic and anti-aldosterone effects of the drug are mentioned in the Clinical Pharmacology section of the label – demonstrates only that the doctor misapprehends the nature of FDA approval as it relates to indication and usage.

Similarly, the declaration of a former FDA official involved in the approval of Bayer's NDA for Yasmin (see Bayer Ex. 7 (Allen Decl.)) – since retained as an expert by Bayer – is insufficient to raise a factual issue as to whether Yasmin is FDA-approved for a use other than oral contraception. Dr. Allen's assertion that an FDA-approved use can be discerned from a reference – in a label's Clinical Pharmacology section – to side effects noted in pre-clinical animal and in vitro studies flatly contradicts the FDA regulation and case law discussed above, and is not credible.

pleadings concerning Bayer's patent infringement claims asserted under 35 U.S.C. § 271(e)(2)(A).

B. Section 271(b) Claims

The Complaint also asserts induced infringement claims against Defendants under 35 U.S.C. § 271(b) (see Cmplt., ¶¶ 45-46, 48-49), which states that "whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Nothing in the record suggests that Defendants intend to promote their generic versions of Yasmin based on the anti-androgenic or anti-aldosterone properties claimed by the '652 patent, however. In their proposed labels, Defendants seek only an indication for oral contraception. (See Def. Ex. E (Comparison of Yasmin Label with Watson Proposed Label), Ex. F (Comparison of Yasmin Label with Sandoz Proposed Label))

Bayer argues that Defendants' proposed labels for their generic versions of Yasmin will induce infringement, because they "do[] not restrict the intended use of [their] product[s] to the creation of a gestagenic effect in patients." (Cmplt. ¶¶ 26, 40) Bayer also alleges that because Defendants' proposed labels disclose drospirenone's pharmacological profile and provide information "regarding the anti-aldosterone and anti-androgenic properties of drospirenone," Defendants "will be marketing [their] ANDA product[s] with specific intent, and/or with the desire to actively induce, aid, and

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Similarly, the declarations establishing that FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) has not objected to Bayer's promotional materials for Yasmin (Bayer Exs. 9, 10) – which make reference to Yasmin's alleged anti-androgenic and anti-aldosterone effects – are not sufficient to create an issue of fact as to the scope of Yasmin's FDA-approved use. Bayer cites no law for the proposition that the FDA's failure to object to marketing materials can broaden the scope of an FDA approved use.

abet infringement of the '652 patent." (Cmplt. ¶¶ 27-28, 41-42) The Warner-Lambert court considered and rejected this precise argument:

> [T]he ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do. . . . The statute explicitly defines the act of infringement as the filing of the ANDA. The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed. Here, the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, as the ANDA does not induce anyone to perform the unapproved acts required to infringe.

Warner-Lambert, 316 F.3d at 1364-65 (emphasis added). Here, as in Warner-Lambert, both Defendants seek FDA approval solely for Yasmin's FDA-approved use of oral contraception. Accordingly, Defendants' ANDAs do not provide a basis for Bayer's induced infringement claims.

The Complaint's remaining allegations are likewise insufficient to state a claim for induced infringement. Bayer alleges, for example, that Defendants are "aware . . . of the widespread use of Yasmin . . . to produce simultaneously a gestagenic, anti-androgenic, and anti-aldosterone effect in premenopausal or menopausal female patients" and that "[t]his use . . . would be readily apparent to [Defendants'] customers. . . ." (Cmplt. ¶¶ 25, 39) Bayer further alleges that Defendants are aware that "a significant proportion of . . . [Yasmin] prescriptions are written with the intent of producing three pharmacological effects – gestagenic, anti-aldosterone, and anti-androgenic," and that Defendants will thus be marketing their ANDA products "with specific intent, and/or with the desire to actively induce, aid, and abet infringement of the '652 patent." (Cmplt. ¶¶ 26, 40)

As the Warner-Lambert court explained, such allegations are insufficient to support an induced infringement claim. In that case, Warner-Lambert contended that the generic manufacturer "had to have 'known' that physicians were prescribing gabapentin for treatment of neurodegeneration" – the use claimed by the patent-in-suit. The Federal Circuit rejected this allegation as a basis for an induced infringement claim, however:

> [M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven. [Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554 (Fed Cir. 1990)] Thus, if a physician, without inducement by [the generic manufacturer] prescribes a use of gabapentin in an infringing manner, [the generic manufacturer's] knowledge is legally irrelevant.

Warner-Lambert, 316 F.3d at 1364.

Bayer's claims for induced infringement pursuant to § 271(b) must be dismissed.[8]

[8] Because Bayer cannot state a claim for patent infringement or induced patent infringement based on its '652 patent, amending the Complaint is futile and leave to amend will not be granted. See Salahuddin v. Cuomo, 861 F.2d 40, 42 (2d Cir. 1988) (noting that a court may dismiss a claim without leave to amend when "the substance of the claim pleaded is frivolous on its face" (citing Moorish Sci. Temple v. Smith, 693 F.2d 987, 990 (2d Cir. 1982)). An action is considered frivolous when, inter alia, "the claim is 'based on an indisputably meritless legal theory.'" Nance v. Kelly, 912 F.2d 605, 606 (2d Cir. 1990) (per curiam) (quoting Neitzke v. Williams, 490 U.S. 319, 327 (1989)). Such is the case here.

CONCLUSION

For the reasons stated above, Defendants' motion for judgment on the pleadings is GRANTED. Bayer's patent infringement claims are dismissed with prejudice. The Clerk of the Court is directed to terminate Defendants' motion. (Docket No. 78)

Dated: New York, New York
September 28, 2010

SO ORDERED.

Paul G. Gardephe
United States District Judge